information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will be asked to discuss supplemental new drug application (sNDA) 20998, for CELEBREX (celecoxib) capsules submitted by Pfizer, Inc., which includes the results from the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen Or Naproxen) trial, a cardiovascular outcomes randomized controlled trial that compared celecoxib to ibuprofen and naproxen, and determine whether the findings of the trial change FDA's current understanding of the safety of these three NSAIDs. In order to interpret some of the PRECISION findings, the committees will also consider the clinical implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 10, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on April 25, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 2, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 3, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Jennifer Shepherd (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06309 Filed 3–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC 2479, Bethesda, MD 20892–2479; telephone: 301- 402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: The following inventions are available for

licensing in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Technology description follows.

Lentiviral Protein Delivery System for RNA-Guided Genome Editing

Description of Technology: This invention provides an HIV–1-based lentiviral vector system for gene correction strategies involving a homologous recombination with a variation of the CRISPR/Cas9 system. Such systems are being explored as potential therapies for certain hereditary diseases. This system comprises (a) a lentivirus vector particle comprising a lentiviral genome which encodes at least one guide RNA sequence that is complementary to a first DNA sequence in a host cell genome, (b) a Cas9 protein, and optionally (c) a donor nucleic acid molecule comprising a second DNA sequence. In addition, the invention provides a host cell comprising the foregoing system, as well as a method of altering a DNA sequence in a host cell comprising contacting a host cell with the foregoing system. Alternatively, the invention also provides a fusion protein comprising a Cas9 protein and a cyclophilin A (CypA) protein, wherein the fusion protein binds to the lentivirus vector particle, as well as a lentiviral vector particle comprising such a fusion protein. Other such lentivirus-based vectors encode a guide RNA, which contains a specific sequence that recognizes a target gene, and a Cas9 endonuclease, which cuts at the specific site. However, such systems present some problems due to constitutive expression of Cas9 endonuclease in lentiviral vector-transduced cells and the large size of the Cas9 gene. The variation of this invention delivers the Cas9 endonuclease directly, instead of the gene encoding the protein.

Potential Commercial Applications: Clinical trials for hereditary diseases such as sickle-cell disease and beta-thalassemia are good market opportunities. Gene correction using the disclosed lentiviral vector system are being tested with respect to the beta-globin gene and the BCL11A gene to treat sickle-cell disease and will be used for induced pluripotent stem cell (iPS) generation.

Development Stage: Early-stage. In vitro data in cell-line models available.

Inventors: Naoya Uchida, Juan J. Haro Mora and John F. Tisdale (NHLBI).

Intellectual Property: US Application No. 62/236,223, filed October 2, 2015 and PCT/US2016/054759, filed September 30, 2016, (NIH Reference No. E–165–2015/0,1).

Publications: Lentiviral protein delivery system for RNA-guided genome editing, PCT Publication No. WO/2017/059241, published April 6, 2017.

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart, Lung and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Denise Crooks at *crooksd@mail.nih.gov.*

Dated: March 22, 2018.

Cristina Thalhammer-Reyero,

Senior Licensing and Patenting Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

[FR Doc. 2018–06364 Filed 3–28–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be open to the public as indicated below, with the attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute Of Child Health And Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NICHD.

Date: June 1, 2018.

Open: 8:00 a.m. to 11:45 a.m.

Agenda: A report by the Scientific Director, NICHD, on the status of the NICHD Division of Intramural Research; talks by various intramural scientists, and current organizational structure.

Place: National Institutes of Health, Building 31A, Conference Room 2A48, 31 Center Drive, Bethesda, MD 20892.

Closed: 11:45 a.m. to 4:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31A, Conference Room 2A48, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Constantine A. Stratakis, MD, D(med)Sci, Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, Building 31A, Room 2A46, 31 Center Drive, Bethesda, MD 20892, 301–594–5984, *stratakc@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/meetings/Pages/index.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 23, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–06259 Filed 3–28–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.